[TEMPLATE for]
AUTHORIZATION to USE and DISCLOSE
PROTECTED HEALTH INFORMATION for RESEARCH[1]
[Name of your HIPAA-Covered Organization]

Principal Investigator: _____
Title of Study: _____
DHS IRB #: _____

Signing this document means you allow us, the researchers in this study, and others working with us to use information about your health for this research study. You can choose whether or not you will participate in this research study. However, in order to participate in this research [and receive research-related treatment[2]] you have to sign both the consent form and this authorization. If you choose not to participate, your choice will not affect any treatment, benefits or services to which you are otherwise entitled.

This is the information we will use: ***[This description must identify the information in a specific and meaningful fashion. Modify this list as appropriate - delete or add items as necessary]***:

- {Name}
- {DOB}
- {SSN}
- {Address}
- {Telephone number}
- {Allergies}
- {Family medical history}
- {Current and past medications or therapies}
- {Information from a physical examination, such as blood pressure reading, heart rate, breathing rate, and temperature}
- ***[List all other tests and procedures that will be performed in the study. These tests and procedures should be fully described in the existing consent form along with the associated risks and discomforts of the tests and procedures]***
- ***[List any other personal health information that will be obtained from other sources to be used in the research record, including prior medical history, tests or records from other sites]***

[1] All other elements of Informed Consent must also be met. See page 28 of DHS IRB Policy.

[2] Do not include this parenthetical phrase, if treatment is not offered as part of the research.

For IRB Use

Others who will have access to your information at _____ **[Insert name of covered entity as appropriate for your study]** for this research project are the _____ **[Insert name of any in-house (covered-entity's) Institutional Review Board]** and authorized members of the _____ **[Insert name of covered entity as appropriate for your study]** workforce who need the information to perform their duties (for example: to provide treatment, to ensure integrity of the research data, and for accounting or billing matters).

[USE THE FOLLOWING 2 DISCLOSURE STATEMENTS, AS APPLICABLE:]

[DISCLOSURE STATEMENT 1: Include the following statement:

{In conducting this study, we may share your information with groups outside the _____ **[as appropriate for your study]**. The information we share may include information that identifies you. These are the groups:} ***[Give the name or other specific identification of the persons or class of persons who will receive the PHI.]***

[For EACH LISTING, include a brief description of WHY they will receive the information. {The examples in brackets {} ***are suggestions only}]***:

- The Department of Human Services' Institutional Review Board (the committee that oversees research studying people);
- {Describe any disclosures required by law; i.e., Center for Disease Control, mandatory reporting of abuse, neglect or exploitation, etc.}
- {Other academic research centers we are working with: ***[list all other academic or other centers including those that may not be within your organization, and explain their roles in project,]*** who are working with the investigators in studying the economic impact of this treatment;}
- {***[Name of group or company,]*** a research data coordinating office that is responsible for collecting results and findings from all the researchers;}
- {***[Name of group or company],*** a pharmaceutical company that may use the results for development of new drugs and/or submissions to the Food and Drug Administration;}
- {***[Name of agency]***, a federal agency that needs to confirm the accuracy of the results submitted to the government;}
- {***[Name of group or company],*** a contract research organization, whose job is to review and correct any mistakes before the results are given to the sponsor or government;}
- ***[Name any other groups and why they will receive the results].***

{Information disclosed to groups outside _____ **[include your organization's/covered entity's name]** may no longer be covered by the federal privacy protections; therefore, your protected health information may be disclosed to others.}

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[DISCLOSURE STATEMENT 2: Describe how you will protect and share de-identified information. Include the following or a similar statement, as applicable:]

{If we share your information with anyone (other than those listed above) outside the _____ ***[insert name of covered entity as appropriate to your study]*** you will not be directly identified by name, social security number, address, telephone number, or any other information that would identify you, unless required by law. Your information will be assigned a unique code number; however, we will keep the key to the code {in a locked file.} ***[OR:]*** {in a password protected computer.}, and will not release that code outside ***[insert name of covered entity as appropriate to your study]***. We will destroy the key to the code at the end of the research study.

[End of the 2 disclosure statements]

[Include revocation clause. Example:]

You may revoke this authorization at any time. **This must be done in writing.** You must either give your revocation in person to the Principal Investigator or the Principal Investigator's staff, or mail it to _____ ***[Insert name and mailing address of PI]***. If you revoke this authorization, we will not be able to collect new information about you, and you will be withdrawn from the research study. However, we can continue to use information we have already started to use in our research, as needed to maintain the integrity of the research.

[Include the following sentence(s):]

{You have a right to inspect and receive a copy of your protected health information.} ***[You may include the following sentence ONLY IF the research includes a treatment component:]*** {However, your personal health information in this study may not be available to you during the study; it will be available after the study is finished.}

[Include one of the following 2 sentences:]

{We will provide you with a copy of the _____'s ***[Name of Covered Entity as appropriate to your study]*** Notice of Privacy Practices, and we will comply with all provisions of this notice.} ***[OR:]***

{Signing this authorization, acknowledges that _____ ***[Name of Covered Entity as appropriate to your study]*** has provided you with a copy of its Notice of Privacy Practices. We will comply with all provisions of the notice.}

[Include one of the following 3 sentences:]

{This authorization does not have an expiration date. We will always keep a copy of your signed authorization.} ***[OR:]***

{This authorization lasts until this study is finished. We will keep a copy of your signed authorization for 6 years after the study is finished.} ***[OR:]***

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{This authorization will expire on _____ [insert the specific date of expiration, if you have a specific date. We will keep a copy of your signed authorization for 6 years after the expiration date.} ***[If you do not know the specific date, use one of the other two optional sentences.]***}

[Include the following sentence above the signature line:]

After you sign this, you will be given a copy with your signature.

I authorize you to use and disclose health information about me for this study, as you have explained in this document.		
_____ Participant's Name	_____ Participant's Signature	_____ Date
_____ Name of person obtaining authorization	_____ Signature of person obtaining authorization	_____ Date

If the participant is unable to give authorization, authorization is given by the following authorized personal representative[3] of the individual:		
_____ Name of authorized personal representative	_____ Signature of authorized personal representative	_____ Date
Describe the representative's authority to act for the individual: _____ _____		

[3] Authorized personal representative is someone who has legal authority to make health care decisions on behalf of the study participant.

For IRB Use